PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 51-566	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US02/39890	International filing date *(day/month/year)* 13 December 2002 (13.12.2002)	Priority date *(day/month/year)* 14 December 2001 (14.12.2001)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/70 and US Cl.: 435/5, 514/44, 50, 120		
Applicant HEMISPHERX BIOPHARMA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10 July 2003 (10.07.2003)	23 March 2004 (23.03.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Terra C. Gibbs Telephone No. (571) 272-0564

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIM[redacted]RY EXAMINATION REPORT

International [redacted]plication No.
PCT/US02[redacted]90

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-18 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 19 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.
PCT/US02[redacted]0

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims NONE	YES
	Claims 1-7	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-7	NO
Industrial Applicability (IA)	Claims 1-7	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-7 meet industrial applicability as defined by PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Carter et al. Carter et al. disclose the studies of synergistic combination of dsRNAs and anti-viral agents in the treatment of viral diseases.

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Ruiz et al. Ruiz et al. disclose HIV patients who intermittently discontinued antiretroviral treatment receive rIL-2 between drug interruptions.

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Birk et al. Birk et al. disclose the kinetics of HIV-1 RNA and resistance-associated mutations after cessation of antiretroviral combination therapy.

Claims 1-7 lack an inventive step under PCT Article 33(3) as being obvious over Carter et al., Ruiz et al., and Birk et al. Carter et al. disclose the studies of synergistic combination of dsRNAs and anti-viral agents in the treatment of viral diseases. Ruiz et al. disclose HIV patients who intermittently discontinued antiretroviral treatment receive rIL-2 between drug interruptions. Birk et al. disclose the kinetics of HIV-1 RNA and resistance-associated mutations after cessation of antiretroviral combination therapy. It would have been obvious to one skilled in the art to devise a method of mitigating the adverse effects of antiviral agents in HIV therapy with the teachings of Birk et al. One of skill in the art would have been motivated to include dsRNA as the antiviral agent since Carter et al. explicitly taught the synergistic combination of dsRNAs and anti-viral agents in the treatment of viral diseases. Therefore the invention would have been obvious to one of skill in the art at the time of filing.